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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,612	07/16/2007	Teruo Okano	GRT/159-102	3397

23117 7590 06/25/2010

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
06/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,612	OKANO ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-16 and 21-26* is/are pending in the application.

4a) Of the above claim(s) *25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-16,21-24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The office action sent 6-11-10 has been vacated in favor of the following office action so as to add a new matter rejection.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-6-10 has been entered.

Claims 2, 4, 17-20 have been canceled. Claims 1, 3, 5-16, 21-26 are pending.

Election/Restrictions

Claim 25 remains directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the non-human animal does not have to be prepared using the method of claim 22. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 25 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 3, 5-16, 21-24 and 26 remain under consideration.

Applicant's arguments filed 4-6-10 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

New Matter

Claims 1, 3, 5-16, 21-24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "polymer having a lower critical temperature for dissolution" in claim 1 is new matter. Support has not been provided for the phrase and none can be found.

The phrase "which has a tumor formed from the sheet of cancer cells, and evaluating the effect of the administered test substance based on increase or decrease in the volume and/or weight of the tumor" in claims 14 and 16 is new matter. Support has not been provided for the phrase and none can be found.

Enablement

Claims 1, 3, 5-16, 21-24 and 26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making a non-human animal having transplanted cancer cells comprising i) preparing a cell culture support coated with poly N-isopropylacrylamide, ii) cultivating cancer cells on the cell culture support at a temperature in which the cells adhere and grow, iii) decreasing the temperature so that the cancer cells detach from the support, and iv) transplanting the

detached cancer cells to a non-human animal, does not reasonably provide enablement for any polymer that changes its hydration force as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 is drawn to a method of making an animal having transplanted cancer cells comprising i) preparing a cell culture support coated with a polymer having a lower critical temperature for dissolution, wherein the polymer is obtained by homo- or co-polymerization of one or more monomers selected from the group consisting of (meth)acrylamide compounds, N- (or N-,N-di)alkyl-substituted (meth)acrylamide derivatives, and vinyl ether derivatives, then, ii) cultivating cancer cells on the cell culture support at a temperature in which the polymer has weak hydration force, iii) adjusting the temperature so that the polymer has a stronger hydration force and the cultured cancer cells detach in a sheet from the cell culture support without being treated with a proteolytic enzyme, and iv) transplanting the detached cancer cells to a non-human animal.

Claim 22 is drawn to a process for preparing a cancer cell-transplanted non-human animal comprising:

(a) preparing a cell culture support coated on a surface, wherein the cell culture support is comprised of a polymer which shifts from a dehydrated state to a hydrated state in the temperature range of 0-80°C, wherein the polymer is obtained by polymerization of one or more monomers selected from the group consisting of

(meth)acrylamide compounds, N- (or N,N-di)alkyl-substituted (meth)acrylamide derivatives, and vinyl ether derivatives;

(b) cultivating cancer ceils on the cell culture support at a temperature at which the polymer is dehydrated;

(c) cooling the cell culture support to a temperature at which the polymer is hydrated, whereby a sheet of cancer cells is detached from the cell culture support without being treated with a proteolytic enzyme; and

(d) transplanting the sheet of cancer cells to a specified site of a non-human animal.

The specification states JP 05/192138 taught a method of "skin cells cultivation comprising the steps of preparing a cell culture support which has a surface of its base coated with a polymer having an upper or lower critical temperature for dissolution in water in a range of 0-80°C, cultivating skin cells on the cell culture support at a temperature not higher than the upper critical temperature for dissolution or at a temperature not lower than the lower critical temperature for dissolution, and thereafter adjusting the temperature to above the upper critical temperature for dissolution or below the lower critical temperature for dissolution, whereby the cultured skin cells are detached. This method depends on temperature adjustment for detaching the cells from the culture base coated with the temperature-responsive polymer."

Example 1 describes a "cell culture base was coated with the temperature-responsive polymer poly(N-isopropylacrylamide) in an amount of 2.0 μg/cm2 and the cancer cells NCI-H460 was cultivated (2 x 104 cells were seeded; 37°C in 5% C02).

Three days later, the cancer cells (NCI-H460) on the culture base were confirmed to have become confluent; thereafter, a cultured cell moving jig comprising a polyacrylic plate coated with a fibrin gel was gently placed over the cultured cell sheet so that the cultured cancer cells adhered to it; then, the cell culture base was cooled at 20°C for 60 minutes. After the cooling, the detached cell sheet was collected from the jig together with the fibrin gel and a piece of the gel with the adhering cell sheet (7 mm x 17 mm x 2 mm; 5 x 10^5 cells) was transplanted subcutaneously to the back of each of 10 nude mice" (pg 13).

Paragraph 16, pg 7-8, teaches the polymer can be obtained by homo- or copolymerization of monomers selected from the group consisting of monomers include (meth)acrylamide compounds, N- (or N,N- di)alkyl-substituted (meth)acrylamide derivatives, and vinyl ether derivatives. However, the specification and the art do not provide adequate guidance that any polymer obtained by homo- or co-polymerization of one or more monomers as broadly claimed would detach in a sheet without being treated with a proteolytic enzyme as broadly claimed other than poly(N-isopropylacrylamide). It would have required those of skill undue experimentation to determine other polymers that would detach in a sheet as claimed because not all of such compounds would work. Therefore, the claims should be limited to using poly(N-isopropylacrylamide).

Applicants' argue the amendment overcomes this aspect of the rejection. Applicants' argument is not persuasive because the specification does not provide adequate guidance that any other polymer obtained by homo- or copolymerization of

monomers selected from the group consisting of monomers include (meth)acrylamide compounds, N- (or N,N- di)alkyl-substituted (meth)acrylamide derivatives, and vinyl ether derivatives would detach in a sheet as claimed. If the polymers on pg 7-8 are capable of detaching cells in a sheet as claimed, then the specific conditions required to detach cells in a sheet are wholly unclear. Applicants do not correlate the poly(N-isopropylacrylamide) polymer to the polymers on pg 7-8 such that those of skill could reasonably expect they change hydration force from 0-80˚ and detach cells in a sheet as claimed. Applicants do not teach the conditions required to detach cells in a sheet using any polymer as broadly claimed.

Claims 1 and 22 encompass transplanting any species of cancer cells into any species of non-human animal. The claims encompass transplanting any species of non-human cancer cells into the same species of non-human animal. Claim 12 is limited to making a nude mouse, rat, mouse, guinea pig, and rabbit. The specification suggests making a nude mouse, rat, mouse, guinea pig, and rabbit and exemplifies making a nude mouse. The specification states any species of cancer cells can be used (pg 6, paragraph 14, line 10-12). However, for the animal to be a model of human cancer, it must comprise human cancer cells. For the animal to support the growth of human cancer cells, it must not reject the cells. The only means described for maintaining human cancer cells in an animal model is if the animal is immunocompromised, and the only immunocompromised animal described by applicants is a nude mouse. If the animal is not immunocompromised, the cancer cells will be attacked by the host's immune system, be destroyed and fail to create a tumor.

The specification does not teach how to use an animal that rejects the cancer cells. The specification does not teach how to use a non-human animal having cancer cells from the same species as a model of human cancer. Overall, the claims encompass too numerous combinations of cancer cells/non-human animals of different species that would not work to be considered "non-operative embodiments", and applicants do not provide adequate guidance to use a non-human animal with cancer cells of the same species as a model of human cancer. Therefore, the claims should be limited to a nude mouse.

Applicants argue cancer cells of one species can be transplanted into a non-human animal of the same species. Applicants' argument is not persuasive. First, the claims encompass an inordinate number of combinations of one species of cancer cells and a different species of non-human animal. At minimum, applicants should amend the claims to exclude the exponential number of non-operative embodiments. Second, applicants do not teach how to use a non-human animal with cancer cells from the same species as a model of human cancer. Therefore, the claims should be limited to a nude mouse.

Claims 14, 16 and 26 are drawn to a method of selecting agents that treat tumors by administering a test substance to an animal before and/or after transplanting cancer cells. The claims are dependent upon the method of claims 1, 3 and 22 respectively; however, the claims are unclear (see 112/2nd). For this rejection, it is assumed the claims are directed to a method of using animals made by the method of claims 1, 3 and 22. The claims are not enabled because the specification does not provide adequate

guidance how to perform the method by teaching the specific steps of administering agents, the controls or how to compare the results so that agents that treat cancer are identified. Without such guidance, applicants have left those of skill with undue experimentation to determine the steps for using animals made by the method of claim 1 to identify agents that treat cancer. Clarification is required.

Applicants argue the steps required to select agents that treat tumors using the non-human animals made by the method of claims 1, 3 and 22 would be known to the skilled artisan. Applicants' argument is not persuasive because it is unfounded. The steps in claims 14 and 16 are not disclosed in the specification as originally filed and are not readily apparent (see New Matter rejection). If the animal and methods of using the animal are known in the art, then why are applicants claiming the animal (claims 13 and 15) and methods of using the animals (claims 14, 16 and 26). If the animal and methods of using the animal are novel, how can the techniques required to use the animal be “conventional?” Overall, the disclosure fails to explicitly or implicitly teach the specific steps of administering agents, the controls or how to compare the results so that agents that treat cancer are identified.

Indefiniteness

Claims 1, 3, 5-16, 21-24 and 26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The temperature “region wherein the polymer has weak hydration force” in claim 1 remains indefinite. The metes and bounds of when a hydration force is “weak” are not

defined in the specification or art at the time of filing. The specification does not teach how to determine when a polymer is in a temperature range that causes a weak hydration force. Without such guidance, those of skill would not be able to determine when they were infringing on the claim.

Likewise, the temperature “at which the polymer has a stronger hydration force” in claim 1 is indefinite. The metes and bounds of when a hydration force is “stronger” are not defined in the specification or art at the time of filing. The specification does not teach how to determine when a polymer is in a temperature range that causes a stronger hydration force. Without such guidance, those of skill would not be able to determine when they were infringing on the claim.

Applicants argue paragraphs 15 and 16 (pg 6-8) define the meaning of “weak” and "strong” hydration force. Applicants' argument is not persuasive. The specification, specifically paragraphs 15-16, and the art at the time of filing do not define when a hydration force is “weak;” therefore, those of skill would not be able to determine when they were infringing on the claim.

The metes and bounds of what applicants consider a “specified site” in claim 1 is indefinite. It cannot be determined how the adjective "specified" qualifies the structure or function of the site receiving the cancer cell transplant. Applicants do not argue this rejection. Deletion of "a specified site of" would overcome this rejection.

Claim 3 as amended remains indefinite because the phrase “wherein the size of a sheet of cancer cells transplanted to the non-human animal” does not clearly refer back to the “detached cancer cells in sheet form” in claim 1. The non-human animal of

claim 1 does not have “a sheet of cancer cells”. Claim 3 should clearly refer to the detached cancer cells in sheet form. Furthermore, it remains unclear what applicants are attempting to limit about the size of the detached cancer cells in sheet form. Claim 1 already allows any size of detached cancer cells in sheet form to be transplanted, and claim 3 merely appears to indicate the size of the detached cancer cells in sheet form can vary which fails to further limit the size of the detached cancer cells in sheet form.

Claim 6 remains indefinite because the metes and bounds of when a cancer cell is from a “transplantable” cell line. Accordingly, the claim does not further limit the structure or function of the cell line.

Claim 7 remains indefinite because the metes and bounds of when a cancer cell is from an “untransplantable” cell line. Accordingly, the claim does not further limit the structure or function of the cell line.

Applicants argue not all cancer cells are transplantable because some would be rejected. Applicants point to Koezuka who used the term. Applicants’ arguments are not persuasive. Cancer cells that would be rejected in one animal would not be rejected in an animal with matching self proteins. Cancer cells that would be rejected by an animal are still "transplantable" despite being rejected. The cells described by Koezuka are still able to be transplanted despite being rejected; Koezuka uses the term to describe cells that are rejected in certain animals. Overall, the claims do not further limit the structure or function of the cell line.

The metes and bounds of claim 9 remain indefinite because all living cells are collected from living tissue. Applicants’ argue the cells are derived from living tissue

and not post-mortem or another cell culture. Applicants' arguments are not persuasive. Post-mortem tissue is still living tissue; cell metabolism does not shut down in all cells immediately. For example, a tumor removed from a deceased person can be removed and put into culture, i.e. it is "living tissue." Furthermore, all tumor cells isolated from culture were derived from "living tissue" at some point as claimed. Overall, the claim does not further limit the cells and does not exclude living cells obtained from post-mortem living tissue.

Claims 14, 16 as amended remain indefinite because the "sheet of cancer cells" lacks antecedent basis. Furthermore, the claims require selecting a substance that increases or decreases the volume and/or weight of a tumor formed from the sheet of cancer cells; however, it is unclear how a substance that increases tumor volume/weight can be an anti-tumor agent as claimed. Finally, the phrase "evaluating the effect of the administered test substance based on increase or decrease in the volume and/or weight of the tumor" is not a clear positive step that sets forth how to evaluate the test substance or what controls are used. Accordingly, the claims are indefinite. Applicants' arguments do not address this rejection.

Claim Rejections - 35 USC § 102

Claims 1, 4-7, 9, 12, 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Koezuka (Nippon Nogei Kagaku Kaishi, 1994, Vol. 68, No. 4, pg 783-792, abstract only) in view of applicants' arguments.

This rejection assumes Koezuka taught a poly(N-isopropylacrylamide) polymer as argued by applicants in the response filed 6-26-09, pg 12, and the conditions required to detach cells in a sheet.

Koezuka taught culturing cancer cells from a primary culture on a thermoresponsive poly(N-isopropylacrylamide) polymer, detaching the cells from the polymer without trypsin and transplanting the cells to nude mice. The conditions described by Koezuka inherently detach cells in a sheet as claimed because the cells are on poly N-isopropylacrylamide polymer and because the conditions are described by applicants as being part of the invention. The claims do not exclude using dextran sulfate or EGTA. Claim 5 is included because it is unclear what applicants consider intimate. Claims 6 and 7 are included because the primary culture described by Koezuka is either a transplantable or untransplantable cell line.

Applicants argue Koezuka differs from the claimed invention because Koezuka used trypsin. Applicants' argument is not persuasive. Koezuka states the method is performed "without trypsin" (4 lines from the bottom).

Applicants argue Koezuka differs from the claimed invention because Koezuka taught collagen, dextran sulfate and EGTA treatment were indispensable conditions. Applicants' argument is not persuasive. The claims use open language and encompass using collagen, dextran sulfate and EGTA treatment. Furthermore, it is not readily apparent from the specification that applicants contemplated excluding collagen, dextran sulfate or EGTA. Specifically, pg 12, line 2, contemplates using collagen.

Claim Rejections - 35 USC § 103

Claims 1, 3, 5-13, 15, 16, 21-24 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Koezuka (Nippon Nogei Kagaku Kaishi, 1994, Vol. 68, No. 4, pg 783-792, abstract only) in view of Sakai (JP 05/192138).

This rejection assumes Koezuka did not teach the conditions required to detach cells in a sheet as now claimed.

Koezuka taught culturing cancer cells from a primary culture on a thermoresponsive N-isopropylacrylamide polymer, detaching the cells from the polymer without trypsin and transplanting the cells to nude mice. Claim 5 is included because it is unclear what applicants consider intimate. Claims 6 and 7 are included because the primary culture described by Koezuka is either a transplantable or untransplantable cell line. The abstract of Koezuka did not teach using poly(N-isopropylacrylamide) polymer.

However, methods of culturing cells with poly (N-isopropylacrylamide) were known in the art as described by Sakai. The specification states JP 05/192138 taught a method of "skin cells cultivation comprising the steps of preparing a cell culture support which has a surface of its base coated with a polymer having an upper or lower critical temperature for dissolution in water in a range of 0-80°C, cultivating skin cells on the cell culture support at a temperature not higher than the upper critical temperature for dissolution or at a temperature not lower than the lower critical temperature for dissolution, and thereafter adjusting the temperature to above the upper critical temperature for dissolution or below the lower critical temperature for dissolution, whereby the cultured skin cells are detached. This method depends on temperature

adjustment for detaching the cells from the culture base coated with the temperature-responsive polymer." A translator at the patent office confirmed the Japanese patent discusses using poly (N-isopropylacrylamide) as the polymer and states 90% of cells could be peeled off in a sheet from the support as in claim 1 and new claim 22 as amended. Thus, the conditions required to detach cells in a sheet are taught by Sakai.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to culturing cancer cells on a thermoresponsive polymer and transplant the cells into nude mice as taught by Koezuka wherein the culturing was performed using the conditions for detaching cells in a sheet described by Sakai. Those of ordinary skill in the art would have been motivated to use the conditions for detaching cells in a sheet described by Sakai for ease of manipulation and to prevent leakage of the cells from the site of transplantation. Since the cells are attached to each other in a sheet, they would be less likely to leak from the site of transplantation.

Applicants argue Koezuka taught using a thermo-responsive poly(N-isopropylacrylamide) polymer and dextran sulfate with trypsin. Applicants' argument is not persuasive. Applicants admit the N-isopropylacrylamide polymer described by Koezuka was poly(N-isopropylacrylamide) as claimed. Therefore, Koezuka may be used as a 102 reference. Secondly, the fourth line from the bottom of the abstract clearly states "without trypsin."

Applicants argue the claimed invention does not require collagen, dextran sulfate or EGTA. Applicants' argument is not persuasive. The claims encompass using (N-

isopropylacrylamide) polymer in combination with collagen, dextran sulfate or EGTA. Furthermore, pg 12, line 2, specifically contemplates using collagen.

Applicants argue the Examiner does not provide adequate guidance indicating the combined teachings of Koezuka and Sakai provide adequate guidance to detach the cells in a sheet as claimed. Applicants' argument is not persuasive. Sakai taught how to detach the cells in a sheet. If Koezuka did not teach the conditions required to detach cells in a sheet, the conditions required to detach cells in a sheet are taught by Sakai and would have been obvious to those of ordinary skill in the art at the time of filing; those of ordinary skill in the art at the time of filing would have been motivated to use the conditions described by Sakai that detached cells in a sheet for ease of manipulation and to prevent leakage of the cells from the site of transplantation. Since the cells are attached to each other in a sheet, they would be less likely to leak from the site of transplantation.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday through Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner